

Individual Safety Report



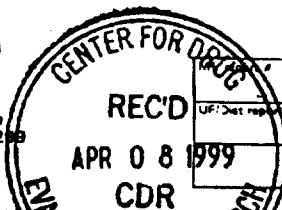
3235249-7-00-01

THE FDA MEDICAL PRODUCTS REPORTING SYSTEM

McNeil

Consumer Healthcare
McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

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Approved by FDA on 11/15/92

UF: Det. report #

FDA use only

A. Patient information				C. Suspect medication(s)			
1. Patient identifier unknown In confidence	2. Age at time of event: or 1 day Date of birth: [redacted]	3. Sex (X) female () male	4. Weight lbs or .09 kgs	1. Name (give labeled strength) #1 TYLENOL Analgesic Unknown #2			
B. Adverse event or product problem				2. Dose, frequency & route used #1 maternal overdose #2			
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 2-3 d prior to mother's adm #2			
2. Outcomes attributed to adverse event (check all that apply) () death 10/24/94 () disability () life-threatening () congenital anomaly () hospitalization - initial or prolonged () required intervention to prevent permanent impairment/damage () other:				4. Diagnosis for use (indication) #1 maternal overdose #2			
3. Date of event (mo/day/yr) 10/24/94		4. Date of this report (mo/day/yr) 04/01/99		5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No () N/A		6. Lot # (if known) #1 Unknown #2	
5. Describe event or problem Medical records from mfr. report #0905668A indicate a STILLBIRTH delivery in a 25-26 week gestation from a mother who took "6 grams/day", 1 gram of unspecified TYLENOL acetaminophen product every 4hrs x 2-3 days PTA. Mother also reported heavy use of cocaine (crack & snorting) first month of pregnancy and use of cocaine 4 days PTA. Mother went to ER on 10/13/94 & was given 2 doses of Tylenol 650 mg. Mother was then admitted to hospital on 10/13/94 with diagnosis of fulminant hepatitis B. On 10/24/94, so sonography confirmed no fetal cardiac motion x5 minutes. Later that day, mother spontaneously delivered stillborn infant girl. An autopsy on infant was performed and the cause of DEATH was listed as an intrauterine fetal demise due to maternal fulminant hepatitis B infection.				7. Exp. date (if known) #1 Unknown #2			
				8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A			
				9. NDC # - for product problems only (if known) -			
6. Relevant tests/laboratory data, including dates 10/13/94 (2000): mother's acetaminophen level=5 (1650 last acetaminophen dose), 10/13/94 mother's drug screen positive for cocaine. RECEIVED APR 08 1999 BY: [redacted]				10. Concomitant medical products and therapy dates (exclude treatment of event) none			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) 9/23/94 mother hepatitis B (+), mother reports heavy use of cocaine during first month of pregnancy				G. All manufacturers			
				1. Contact office - name/address (& mfring site for devices) McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034 DSS APR 09 1999 ADVERSE EVENT REPORTING SYSTEM			
				2. Phone number 215-273-7820			
				3. Report source (check all that apply) () foreign () study () literature () consumer health professional (X) professional () user facility company representative () company representative () distributor () other:			
				4. Date received by manufacturer (mo/day/yr) 03/29/99			
				5. (A) NDA # 19-872 IND # PLA # pre-1938 () Yes OTC product (X) Yes			
				6. # IND, protocol #			
				7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic (X) Initial () follow-up #			
				8. Adverse event term(s) STILLBIRTH DEATH			
				9. Mfr. report number 1152014A			
				E. Initial reporter			
				1. Name, address & phone # [redacted] MD [redacted] [redacted] [redacted]			
				2. Health professional? (X) Yes () No			
				3. Occupation physician			
				4. Initial reporter also sent report to FDA () Yes () No (X) Unk			



Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.